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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/697,943

10/31/2003

Klas Stoltz

STOLTZ11

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

05/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/697,943	Applicant(s) STOLTZ, KLAS	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 10-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/26/2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 10/26/2006, amendment(s) to the specification and amended claim(s) 1 and 5 is/are acknowledged. The current rejections of the claim(s) 1-9 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Priority

2. The examiner notes the identification of this application as a national stage filing under 35 U.S.C. 371 based on PCT/SE02/00951 filed on 07/05/2002.
3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Sweden on 05/17/2001.

Election/Restrictions

4. Applicant's election without traverse of Group I, drawn to claims 1-9, in the reply filed on 02/12/2007 is acknowledged.
5. Claims 10-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/12/2007.

Specification

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Gu et al. (US 5,971,942, hereinafter Gu).

9. For claim 1, Gu discloses a swallowable, digestive-fluid sampling capsule (the sampler positively recited in the abstract) as best seen in Figures 1-4, comprising:

- a capsule wall (10) defining at least one inlet opening (20);
- an inner chamber (40) defined by said capsule wall operable effective to hold vacuum or negative pressure relative to the environment, wherein said inlet opening is sealably engaged (abstract); and
- a blocking member (the edges of wall 10) disposed in said inner chamber adjacent to said inlet opening in said capsule wall (as best seen in Figures 2B and 2C),
- wherein said blocking member comprises an elastic material that is operably configured to (a) permit fluid flow of a body substance into said inner chamber as long as a pressure difference exists between said inner chamber and an external environment of the capsule following contact with the body substance and (b) prevent fluid flow through said inlet opening from the inside of the chamber to the exterior environment when said pressure difference has been equalized (column 2 lines 23-33).

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10. For claim 2, Gu discloses a swallowable, digestive-fluid sampling capsule, wherein said inlet opening is sealed by a plug member (30) of a material that is dissolved following contact with said body substance (abstract).

11. For claim 3, Gu discloses a swallowable, digestive-fluid sampling capsule, wherein said blocking member consists of an elastic, operably self-sealing membrane, which in a fluid flow preventing configuration sealingly bears on the inside of said capsule wall effective to prevent an outflow of the body substance in the inner chamber (column 1 lines 6-8 and column 2 lines 23-33).

12. For claim 7, Gu discloses a swallowable, digestive-fluid sampling capsule, wherein said plug member consists of two or more layers of different dissolvable materials (column 2 lines 13-20).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 4-6 and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gu in view of Pawelec (US 4,481,952).

15. Gu discloses the claimed invention, including a bell-shaped blocking member (as best seen in Figures 1-4), except for explicitly disclosing a capsule wherein (a) the capsule comprises two members, a cap member and a body member that are permanently joined to each other and disposing the blocking member therein; (b) the

blocking member having at least one laterally located aperture to establish fluid communication of a body substance with said inner chamber; (c) a peripheral edge of said blocking member is disposed between said cap member and said body member; (d) a filter is disposed between said cap member and said body member; and (e) protrusions are externally disposed on said capsule oriented circumferentially with respect to said inlet opening thereby forming inlet grooves.

16. Pawelec discloses a swallowable, digestive-fluid sampling capsule (G), wherein (a) the capsule comprises two members, a cap member (46a) and a body member (46b) that are permanently joined to each other and disposing the blocking member (9) therein; (b) the blocking member having at least one laterally located aperture (16) to establish fluid communication of a body substance with said inner chamber; (c) a peripheral edge of said blocking member is disposed between said cap member and said body member (as best seen in Figures 12 and 13); (d) a filter (12) is disposed between said cap member and said body member; and (e) protrusions (the enlarged portions of element 14) are externally disposed on said capsule oriented circumferentially with respect to said inlet opening thereby forming inlet grooves (as best seen in Figures 12 and 13).

17. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the swallowable, digestive-fluid sampling capsule as taught by Gu, with the swallowable, digestive-fluid sampling capsule as taught by Pawelec for the purpose of increasing the efficacy of an physiologically-triggered device to automatically obtain and secure samples for diagnosis.

Response to Arguments

18. Applicant's arguments filed 10/26/2006 with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

19. The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Gross (US 5,318,557) discloses swallowable, digestive-fluid sampling capsule.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is

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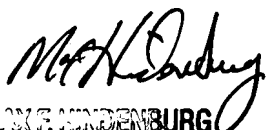
(571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MAX F. HINDENBURG
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